



Job Description			
Job Title:	Auditor, Quality and Compliance	Job Category:	Exempt <input checked="" type="checkbox"/> Non-Exempt <input type="checkbox"/>
Department/Group:	Alliance Foundation Trials, LLC (AFT)	Reports to:	Director, Quality Management and Compliance
Location:	Chicago or Boston Office	Travel Required:	Approximately 50%
Level/Salary Range:	\$	Position Type:	Full-Time <input checked="" type="checkbox"/> Part-Time <input type="checkbox"/> Contract <input type="checkbox"/> Temporary <input type="checkbox"/>
HR Contact:	Director of Human Resources	Date posted:	
External posting URL:			
Internal posting URL:			
<p>Alliance Foundation Trials, LLC (AFT) sponsors and conducts high-quality cancer clinical trials funded exclusively by non-NCI (National Cancer Institute) sources. AFT leverages the internationally recognized scientific experts and thought leaders of the Alliance for Clinical Trials in Oncology with its expansive and established network of hospitals, medical centers, and community clinics across the North America.</p> <p>In May 2014, the Foundation created Alliance Foundation Trials, LLC (AFT), which is a wholly owned subsidiary of the Foundation. It was also created to conduct cancer clinical research and address medical care and treatment through large-scale clinical trials involving various industry-related partners.</p>			
<p>Purpose/Scope:</p> <p>The auditor is responsible for conducting clinical study audits of investigator sites and third party organizations (TPOs) and internal departments, writing reports and maintaining audit records. Working with the QMC team, participates in the assessment and development of Corrective and Preventative Action (CAPA).</p>			
<p>ROLE AND RESPONSIBILITIES</p> <ul style="list-style-type: none"> • Manage internal Quality Audits, CAPA, Quality Management Reviews, and Quality Audit, in conjunction with the Director of Quality Management & Compliance and the QMC team • Develop the investigator sites and TPO site audit schedule, including identification of TPOs and sites to be audited in a yearly basis to be approved by the QMC Director and QMC Manager • Lead qualification, routine and for-cause audits of TPOs and investigator sites to assess effectiveness of quality management systems (QMSs), compliance to approved clinical study protocols and applicable regulations • Ensure timely issuance of audit reports, audit observation forms, oversee audit response process and drive audits to closure • Maintain and enhance procedures for communicating audit observations and tracking audit responses • Contribute to quality and compliance process improvements • Develops metrics and indicators to identify audit trends and improve key quality determinants of 			



all aspects of GCP operations

- Approximately 50% travel is required to conduct investigator site and TPO audits.
- Perform other related duties as assigned

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Bachelor of Science or Bachelor of Arts degree required, preferably in a relevant scientific discipline
- At least 3-5 Years GCP QA auditing/monitoring experience
- ASQ, Auditor, CCRP, or ACRP accreditation preferred

Candidates must demonstrate the following competencies:

- Manage interpersonal relationships by interacting and communicating with clarity, tactfulness and courtesy with internal and external personnel
- Communicate effectively, both orally and in writing
- Organizational and prioritization skills
- Work effectively as a part of a team and independently with minimal supervision
- Ability to work under pressure and coordinate multiple tasks
- Attention to detail
- Time management, multi-tasking, problem solving, and effective communication skills
- Proficient in MS Office suite (MS Office products, Word processing, Excel spreadsheets, e-mail management and good etiquette)

ADDITIONAL NOTES

The above statements are intended to describe the general nature and level of work being performed by people assigned to this job. This is not an exhaustive list of all duties and responsibilities associated with it.

Approved By:	Majagamy Ramos_Bordonaro	Date:	7/24/20
Last Updated By:	Heather Choukri	Date:	7/27/20

Employee Name:

Date:

Employee Signature: _____